NOTICE OF AVAILABILITY OF FUNDS for NATIVE AMERICAN RESEARCH CENTERS FOR HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES
INDIAN HEALTH SERVICE
NATIVE AMERICAN RESEARCH CENTERS FOR HEALTH

AGENCY: Indian Health Service

ACTION: Program Announcement of Funds for Native American Research Centers for Health

SUMMARY: : The Indian Health Service (IHS), in association with the National Institute of General Medical Sciences (NIGMS), announces an initiative to support Native American Research Centers for Health (NARCH) which will develop opportunities for conducting research and research training responsive to the needs of American Indian/Alaska Native (AI/AN) communities. Competitive grant applications for fiscal year (FY) 2002 are now being accepted. There will be only one funding cycle for FY 2002. Grants will be administered in accordance with applicable Office of Management and Budget (OMB) circulars, Department of Health and Human Services grant regulations at 45 C.F.R. Parts 74 and 92, the Public Health Service Grants Policy Statement, and other applicable Departmental, IHS, and NIH policies and procedures such as the regulations governing protection of human subjects at 45 C.F.R. Part 46. Applications are not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

DEADLINES
Application Receipt Date: December 12, 2001

PURPOSE: The NARCH initiative will support partnerships between AI/AN tribes or of tribal-based organizations such as the National Indian Health Board and Area Health Boards, and institutions that conduct intensive academic-level biomedical and behavioral research; these partnerships are called Native American Research Centers for Health. The purposes of the NARCH initiative are: to develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, and behavioral research who will be competitive in securing NIH funding; to increase the capacity of both research-intensive institutions and AI/AN organizations to work in partnership to reduce distrust by AI/AN communities and people toward research; and to encourage competitive research linked to the health priorities of the AI/AN organizations and to reducing health disparities. These purposes will be achieved by supporting student development projects, faculty development projects, and research projects (including pilot projects) developed by each NARCH partnership.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS led national activity for setting priority areas. This Program Announcement (PA), Native American Research Centers for Health, is related to one or more of the priority areas. Potential applicants may obtain a copy of Healthy People 2010 at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS
   The proposed NARCH must be a working partnership of the AI/AN organization and of the research-intensive institution. Applicants eligible to receive a NARCH award are the AI/AN organizations of the partnerships. As the grantee, the AI/AN organizations will define criteria and eligibility for participation in all aspects of the partnership, consistent with this announcement. A minimum of 30% of the grant funds must remain with that AI/AN

organization, that is, no more than 70% may be subcontracted to other institutions or organizations.

The AI/AN applicant must be one of the following:

* a federally recognized Indian tribe or tribally sanctioned non-profit tribal organization; or
* a non-profit national or area Indian health board; or
* a consortium of 2 or more of those tribes, tribal organizations, or health boards.

Applicants are strongly encouraged to establish eligibility of their proposed applications prior to submission. Inquiries about eligibility should be sent to William L. Freeman, M.D., M.P.H. at the address listed under INQUIRIES.

The Research-Intensive Partner must be an accredited public or private nonprofit university or other institution: that has an established record of conducting research into the health problems of AI/ANs; that has demonstrated a commitment to enhancing the capability of AI/AN faculty, students, investigators, and communities to engage in biomedical, behavioral, and clinical research; and that has demonstrated a commitment to mentoring AI/AN faculty, students, and investigators.

The proposed NARCH must have a Community and Scientific Advisory Council with more than 50% of its membership being appointed by the AI/AN applicant.

The proposed NARCH may include additional affiliated organizations, e.g., tribal colleges, additional colleges or universities, additional tribes, or other Indian communities or organizations. NARCH applicants are encouraged to have an affiliation with an applicable component of the IHS for technical and other in-kind support, such as linking data from IHS and others to understand better the health status of the involved tribes or communities.

Principal Investigator: The Principal Investigator, the individual responsible for the administration (including fiscal management) of the overall project, must have his/her primary appointment with the AI/AN applicant organization. Special arrangements of employment, such as inter-organizational personnel agreements, are permissible. The Principal Investigator may be, but is not required to be, the NARCH Program Director or a Research Project Investigator.

NARCH Program Director: The NARCH Program Director is the individual responsible for the day-to-day leadership and management of the research and training programs within the proposed NARCH. The Program Director may be, but is not required to be, the Student and Faculty Development Director or a Research Project Director.

Student and Faculty Development and Project Participants:

The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on the continual development of students and faculty. In order to be included as the Student and Faculty Development Director, the prospective director: must have a faculty appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner; and must show that the director has the knowledge, skills, and capabilities to mentor students and faculty and to generate and direct development and mentoring programs. The Student and Faculty Development Director may be the NARCH Program Director.

Faculty and students may be supported in research education activities that improve their skills and abilities to be successful at the next stage of their professional development. To be included for faculty development in the proposed NARCH, the individual must have a faculty appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner.

Research Project Investigators: The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on continual improvement of the research competitiveness of the research investigators. In order to be included as a research project investigator in the proposed NARCH, a prospective investigator: must have a faculty appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner; and must show that the investigator has the need, based on institutional, departmental, and professional development plans, to enhance his/her research knowledge, skills, and capabilities by engaging in the proposed research program and associated activities.

TRIBAL APPROVAL OF THE APPLICATION

It is the policy of the IHS that all research involving AI/AN tribes be approved by the tribal governments with jurisdiction. The following documentation, therefore, is required as part of the application.

If the applicant is a federally recognized Indian tribe, a resolution of support from the tribal government must be

part of the application. Applications that affect more than one Indian tribe must include resolutions of support from all affected tribes. If the applicant is an eligible consortium of tribes, a resolution of support from each tribe of the consortium must be included. If the applicant is a tribally sanctioned nonprofit tribal organization, specific tribal resolution(s) of support will not be required if the current tribal resolution(s) under which the organization operates encompasses the proposed application. (A copy of the current operational resolution(s) must be submitted with the application.) The official final signed resolution must be received by the Grants Management Branch, IHS, no later than April 30, 2002. A grant will not be awarded unless the final signed resolution is received by this date.

If the applicant is a nonprofit national or area Indian health board, or is an eligible consortium of those Indian health boards, it is not required to submit a resolution. However, the applicant organization must submit a letter of support signed by the executive director of each health board involved, specifically citing the research project proposed. Each AI/AN organization that derives benefit from the grant must also submit such a letter.

MECHANISM OF SUPPORT

Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS, and will be reviewed using the NIH S06 mechanism. The responsibility for planning, directing, and executing the program, as well as data acquisition and analysis and evaluation of the proposed program, lies solely with the applicant organization. The maximum grant period may not exceed four years, with the opportunity for competing renewal at the end of that period.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be $1.5 million in Fiscal Year 2002. The actual amount may vary, depending on the response to the PA and availability of funds. Three to five awards are anticipated.

An application may request a project period not to exceed four years of support, and direct costs not to exceed $700,000 in the first year. Direct costs to the applicant include the entire cost of each subcontract--that is, each subcontract's direct cost plus the subcontract's appropriate facilities and administration (F&A) cost. Because it is anticipated that all budget requests will exceed $250,000, the modular grant requirements would not apply to this PA. A minimum of 30% of the grant funds must remain with the applicant organization.

TECHNICAL ASSISTANCE WORKSHOPS

The IHS and NIGMS together will conduct a technical assistance and information sharing workshop about this grant initiative. It will be held Thursday, September 20, 2001, in Denver, CO. People planning to attend are asked to notify either Ms. Patricia Gregory or Mr. Pallop Chareonvootitam, telephone (301) 443-5204, FAX (301) 443-9602, e-mail PGregory@HQE.ihs.gov or PChareon@HQE.ihs.gov, of the name of each person and of the organization each represents, no later than Thursday, September 13, 2001, to help insure that IHS and NIGMS bring enough copies of materials to the workshop. The details of the location of the workshop can be obtained from Ms. Gregory or Mr. Chareonvootitam.

BACKGROUND

The AI/AN tribal nations and communities have long experienced poorer health status than other Americans. Although major gains of reducing health disparities were made in the last half of the twentieth century, most gains stopped by the mid 1980s (Trends in Indian Health 1998-99). A few diseases, e.g., diabetes, got worse. "All Indian" rates contain marked variation among the "IHS Areas" or regions (Regional Differences in Indian Health 1998-99); variation by tribe exists within Areas as well. Although the "All Indian" mortality rates for all cancers are about 20% lower than the US rates for all races, there is variation among IHS Areas for specific cancers; moreover, the favorable AI/AN mortality rates for some cancers may be due to markedly lower incidence rates partly offset by higher case-fatality rates (NIH Publication 98-4247). Unfamiliarity with modern health care may adversely influence health status among the elderly, the low-income elderly, and tribes, and also may reduce the acceptability of health research among them. The daunting tasks confronting tribes, researchers, and health care and public health programs in the beginning of the twenty-first century are to resume the reduction of health disparities that had occurred up to the 1980s, to reverse the worsening in a few diseases, to maintain and strengthen the favorable status, and to reduce the disparities among and within Areas and tribes.

Factors known to contribute to health status and disparities are complex, and include underlying biology, physiology, and genetics, as well as ethnicity, culture, socioeconomic status, gender/sex, age, geographical access to care, and levels of insurance. Additional factors known to contribute to health status and disparities include: family,

home, and work environments; health practices; social support systems; lack of access to culturally-appropriate health care; and attitudes toward health. Yet none of these alone or in combination accounts for all documented differences.

Health disparities of AI/ANs may also reflect a lack of research relevant to improve their health status. Many AI/ANs distrust research for historical reasons. One approach that combats this distrust is to ensure that tribes are senior partners in training and research that involves them, as for example in community-based participatory research. This approach is especially helpful to design both training relevant to researchers from tribal communities, and research relevant to the health needs of the communities.

The mission of NIH is to acquire new knowledge that will lead to better health by understanding the processes underlying health and disease, that in turn will help prevent, detect, diagnose, and treat disease and disability. The NARCH initiative works toward the NIH mission by supporting research that discovers the interrelationships among the many factors that contribute to health and disease, and by helping train and promote researchers concerned with AI/AN health. In addition, the NARCH initiative is based on tribes as senior partners in training and research.

OBJECTIVES

Due to the complexity of factors contributing to the health and disease of AI/ANs, and to their health disparities compared with other Americans, the collaborative efforts of the agencies of the Department of Health and Human Services, and the collaboration of researchers and AI/AN communities, are needed to achieve significant improvements in the health status of AI/AN people.

Develop a Cadre of AI/AN Scientists and Health Professionals Engaged in Research: The NARCH initiative offers opportunities to develop more AI/AN scientists and health professionals engaged in research, and to conduct biomedical, clinical, and behavioral research that is responsive to the needs of the AI/AN community and the goals of this initiative. Faculty and students at each proposed NARCH will be supported through science education projects designed to increase the numbers of, and to improve the research skills of investigators involved with AI/ANs, and through investigator-initiated, scientifically meritorious research projects, including pilot research projects.

Enhance Partnerships: Recent community-based participatory research suggests that AI/AN communities can work collaboratively in partnership with health researchers to further the research needs of AI/ANs. Fully utilizing all cultural and scientific knowledge, strengths, and competencies in such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors either promoting or hindering improved health status of AI/ANs, and generate the development and evaluation of interventions to improve their health status.

Reduce Health Disparities: In the Indian Health Care Improvement Act, Public Law (P.L.) 94-437, as amended, IHS was legislatively mandated to improve the delivery of effective health care to AI/ANs. In the NIH Revitalization Act of 1993, NIH was encouraged to increase the number of underrepresented minorities participating in biomedical, clinical, and behavioral research, including studies on drug abuse and alcoholism, and the examination of the role of resiliency in the prevention and treatment of those conditions. Also, the "Initiative to Eliminate Racial and Ethnic Disparities in Health" by HHS (http://raceandhealth.hhs.gov) encouraged NIH to help reduce health disparities. NIH published a draft "Strategic Research Plan to Reduce and Ultimately Eliminate Health Disparities" (http://www.nih.gov/about/hd/strategicplan.pdf). Finally, the "NIGMS Strategic Plan for Reducing Health Disparities" http://www.nigms.nih.gov/news/reports/health_disparities.html) presents an NIGMS role in health disparity reduction through its focused programs on research infrastructure to increase the number and capabilities of underrepresented minority health researchers. In response to these priorities, the IHS and NIGMS have established a collaboration to support Native American Research Centers for Health.

Reducing health disparities among AI/AN communities and individuals may be fostered by greater understanding of how to enhance their strengths and resiliencies. While AI/AN communities have relied on health research and medical science to reduce health disparities, they also have relied on their own psychological, organizational, and cultural, assets and strengths to survive major harms and disruptions over the centuries, and to rebound from insults to health. (For research about resiliencies, see http://www.nida.nih.gov/ResilandRiskWG/ResilandRiskWG.html.)

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included

in all NIH supported biomedical, clinical, and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of P.L. 103-43). Because the NARCH initiative targets AI/AN people and communities, a minority population, only the policy of inclusion of women applies to this PA.

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html; a complete copy of the updated Guidelines are available at: http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm. The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects' research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain copies of these policies from the initiative staff listed under INQUIRIES. Initiative staff may also provide additional relevant information concerning the policy.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The OMB Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the title of the proposed NARCH, the name, address, and telephone number of the Principal Investigator and its Program Director, the identities of the partners and of key personnel, and the number and title of this PA. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows the IHS and NIH Center for Scientific Review (CSR) staffs to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to the initiative staff listed under INQUIRIES by the letter of intent receipt date

listed in the heading of this PA.

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (Rev. 5/2001) at http://grants.nih.gov/grants/forms.html are to be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable, PDF format. Although applicants are strongly urged to begin using the 5/2001 revision of the PHS 398 as soon as possible, NIH will continue to accept applications prepared using the 4/1998 revision until January 9, 2002. Beginning January 10, 2002, however the NIH will return applications that are not submitted on the 5/2001 version. For further assistance contact GrantsInfo, telephone (301) 435-0714, e-mail: GrantsInfo@nih.gov.

Applicants are strongly urged to contact NARCH initiative staff at an early stage to request the specific supplementary instructions for the PHS 398 for the NARCH grants. Application kits and supplementary instructions may be obtained from the initiative contacts listed under INQUIRIES.

A supplemental application to an existing NARCH program may be submitted if the supplemental application is within the first 12-month period of a four-year NARCH grant, if the total number of projects in the parent grant plus the supplemental application does not exceed five (5) research projects and five (5) pilot research projects, and if the direct costs (including all subcontract costs) of the parent grant plus the supplemental application do not exceed $700,000 in the first year of supplement. A supplemental application may not extend beyond the project period of the parent NARCH grant. Supplemental applications are to use the grant application form PHS 398 (Rev. 5/2001), and should follow the supplementary instructions for Form PHS 398 for NARCH grants. The receipt dates for the Letter of Intent and Application, the instructions about the original and photocopies, and all requirements for and limitations on original NARCH applications apply to supplemental applications. Because the reviewers will not have the original application, the supplemental application should be self-contained and complete in itself.

The Request For Application (RFA) label available in the PHS 398 (Rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type this RFA number "GM-02-001" on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, this PA title "Native American Research Centers for Health" and the RFA number must be typed on line 2 of the face page of the application form and the YES box must be marked.

The sample RFA label available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in .pdf format.

Submit a signed, typewritten original of the application, including the Checklist, and one (1) single-sided photocopy of the entire signed application (including Appendices and supporting documents) in one package to:

Grants Management Branch
Indian Health Service
Twinbrook Metro Plaza, Suite 100
12300 Twinbrook Parkway
Rockville, MD 20852-1750
Telephone: (301) 443-5204
(for express or courier service, the Zip code is unchanged).

At the time of submission, four (4) additional single-sided photocopies of the complete signed original application, including the Checklist, Appendices, and supporting documentation, must also be sent to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 2030 - MSC 7720
Bethesda, MD 20892-7720
Telephone: (301) 435-0715
or Bethesda, MD 20817 (for express or courier service).

Applications must be received by the application receipt date listed in the heading of this PA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR

will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

APPLICATION CONTENT

The purposes of the NARCH initiative are: to develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, and behavioral research that is competitive to NIH funding; to increase the capacity of both research-intensive institutions and AI/AN organizations to work in partnership to reduce distrust by AI/AN communities and people toward research; and to encourage competitive research linked to the health priorities of the AI/AN partner and to reducing health disparities. A proposed NARCH, therefore, may include any or all of the following components: student development projects; faculty development projects; research projects (including pilot projects); or "core" administrative facility.

The content of the application should explain the components of the application, and how they help meet the purposes of the NARCH initiative.

* A description should be provided of the current state of the research and research training enterprise at the proposed NARCH and its institutional and community partners, including faculty and student profiles.

* A clear statement should be presented of the overall goals, specific measurable objectives, and anticipated milestones; these elements should be presented in the context of needed improvements in the partners' organizational infrastructure and environment for research.

*Documentation should be given that the research-intensive partner is an institution with an established record of conducting research into the health of AI/ANs, and that it has a demonstrated commitment to the special encouragement of, and assistance to, AI/AN faculty, students, investigators, and communities for enhancing their capacity to engage in biomedical research.

* Documentation about the nature of the partnership itself should be included, such as: the process to develop the application and proposed NARCH itself; and the past and future efforts to increase the capacity of the partners, to improve their partnership, and to contribute to the success of the NARCH.

* A plan for assessment of the benefits of the activities by the proposed NARCH on specific, measurable outcomes identified in the application should be provided. IHS and NIGMS recognize that tribes, tribal-based organizations, and research-intensive institutions are diverse in their mission, their health and economic statuses, and their cultures. Such an assessment could include a self-study by the proposed NARCH and its partners, which focuses on fact-finding, program evaluation, and recommendations for improvement in key areas.

* Strategies for determining the initial and ongoing success of their efforts for organizational development should also be presented. It is expected that each proposed NARCH will develop its own set of strategies that best match its circumstances.

Guidance and suggestions for program evaluation of a proposed NARCH can be obtained from http://www.the-aps.org/education/promote/promote.html.

Student Development Projects

If student development projects are proposed, the NARCH application should describe new programs, modifications, or additions to existing programs of the partners, that encourage and facilitate AI/AN students to enter, advance, and remain in research careers. Such projects might include, but are not limited to, providing employment as research assistants in research projects of research-active mentors with an explicit mentoring plan, providing other mentoring with an explicit mentoring plan, providing workshops to improve technical or communication skills, providing motivating seminars or journal clubs highlighting problems of interest to students, providing contact with role models, and providing opportunities to travel to present results at national scientific meetings.

If research mentorships or apprenticeships are proposed, the application should clearly document the experience, proposed commitment, and quality of the mentors in providing guidance and advice to students (including responsible conduct of research and research integrity, teaching, and protection of human subjects), and in fostering the development of academic and community-based AI/AN researchers.

The application must clearly describe how the development plans for students will meet both the individual's professional development goals, and one purpose of the NARCH initiative: to develop a cadre of AI/AN scientists and health professionals.

The application must have an evaluation plan for the project(s) that indicates the anticipated outcomes relative to

the current baseline data. For example, one outcome might be the improved retention of students in science majors. The application should indicate the anticipated (quantitative) improvement relative to the current retention rate.

A student in a NARCH Student Development Project must be a full-time or part-time student officially enrolled in an educational program leading to an undergraduate or graduate degree, or in a post-doctoral educational program, or (if well justified) in late high school.

A helpful book about mentoring science students is found at http://books.nap.edu/catalog/5789.html.

Faculty Development Projects

If faculty development projects are proposed, the NARCH application should describe the need, proposed activity, and anticipated outcomes. Faculty development projects might include, but are not limited to, short-term mentored research experiences in the lab of an active NIH-extramurally-funded researcher with an explicit mentoring plan, long-term general mentoring under an explicit mentoring plan, or attendance at workshops or courses or national meetings needed for acquiring specific skills or methodologies needed for prospective research.

As with student development projects, the application should document the experience, proposed commitment, and quality of the mentors, teachers, or experience in providing guidance and advice to faculty, and in fostering the development of academic and community-based AI/AN research.

The application must also describe the evaluation plan for the faculty development project. Release time for preparing proposals or mini-research projects, not reviewed as pilot projects, is not allowed.

The application must clearly describe how the development plans for faculty will meet both the individual's professional development goals, and two purposes of the NARCH initiative: to develop a cadre of AI/AN scientists and health professionals, and to enhance the partnership of the proposed NARCH.

Research Projects

NARCH applications may include a maximum of five (5) research projects and a maximum of five (5) pilot research projects. Unlike regular research projects, a pilot research project is limited in scope and is not expected to have preliminary data. It is also limited to a budget of no more than $35,000 direct costs per year for four years. The pilot research project is intended for faculty without current research support. Support for faculty participating in pilot research projects is preparatory to seeking more substantial funding from NIH research grant programs (e.g., Academic Research Enhancement Award [AREA], K, and R01 awards), as well as funding from other agencies and private sources. Funds received from the proposed NARCH to support pilot research projects may not be used to supplement ongoing research projects. A NARCH application need not include both research projects and pilot research projects. Applications for only pilot research projects or for only research projects may be submitted. Individual project investigators may propose either a research project or a pilot research project, but not both. In addition, the NARCH application must show that each participating investigator has the need, based on institutional, departmental, and professional development plans, to develop or enhance his/her research knowledge, skills, and capabilities by engaging in the proposed research program and associated activities.

Research projects (including pilot research projects) proposed under this initiative must be in research areas normally funded by any of the National Institutes of Health. Research projects addressing health disparities and the health priorities of the AI/AN partner are especially encouraged.

A listing of grants recently funded by NIH may be found at CRISP (Computer Retrieval of Information on Scientific Projects), a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions. It may be accessed at https://www-commons.cit.nih.gov/crisp/.

Each research project or pilot research project should follow the instructions provided in PHS 398 (Rev. 5/2001) for preparing research grant applications. The application must clearly describe how the proposed research plan will meet both the individual's professional development goals, and the three purposes of the NARCH initiative: to develop a cadre of AI/AN scientists and health professionals; to enhance the partnership of the proposed NARCH; and to conduct competitive research linked to the health priorities of the AI/AN partner and to reducing health disparities. The professional development goals must clearly describe specific objectives and milestones. The goals should include, but are not limited to, improving competitiveness in winning grant support, and should describe how successful completion of the proposed research project will improve the research skills of, and will help develop, the students and faculty, thus contributing to the overall goals and specific measurable objectives of the proposed NARCH.

Each research project or pilot research project must follow the IHS policy concerning tribal approval, that all research involving AI/AN tribes be approved by the tribal governments with jurisdiction. That is, each project that involves people or community[ies] of an AI/AN tribe, or an eligible non-profit organization, must include a resolution of approval from the tribal government[s], or (if applicable) a letter of support signed by the director of

the eligible AI/AN organization, or both (if applicable).

Administration of the overall NARCH
The administrative personnel, facilities, and programs of the overall NARCH should be described. It is permissible but not necessary to have a set of core support programs, that provide common scientific services to two or more NARCH projects.

Supplemental Applications
A supplemental application must include an Introduction. The Introduction to the supplemental application should contain an overall description of the nature of the supplement and how it will enhance the current NARCH program. All revised subproject applications in a supplemental application must include an Introduction that summarizes the substantial additions, deletions, and changes, as well as responses to the criticisms and issues raised in the scientific review summary statement of the original subproject. The changes in each subproject must be clearly marked by appropriate bracketing, indenting, or changing of typography. If changes are so extensive they include most of the text, explain this in the subproject's Introduction. All requirements for and limitations on original applications apply to supplemental applications. Because the reviewers will not have the original application, the supplemental application should be self-contained and complete.

ALLOWABLE COSTS
Administrative Costs
   Certain administrative costs for managing a comprehensive program are allowable and may vary, depending upon the size and complexity of the program's activities. The costs budgeted for NARCH grants and subcontracts may not duplicate items already budgeted in other cost centers of the AI/AN, research-intensive, and subcontracted organizations and institutions, such as accounts which make up the Facilities and Administration (F&A) cost pool. The grantee organization receiving the award must be prepared to provide documentation showing the direct relationship of proposed costs to the program and that costs of this type are charged in a uniform manner to all other grants at all institutions and organizations participating in the award.
   Salary (up to 25 percent effort, although it should generally be less) for the NARCH Program Director is allowable for that portion of time or effort specifically employed in directing the proposed NARCH. (The 25% limit does not include salary for being a research investigator.) Limited salary support for secretarial or clerical help is allowable only when in direct support of the proposed NARCH. For guidance, applicants should refer to the OMB Circular appropriate for them, A-87 (Cost Principles for State, Local, and Indian Tribal Governments, http://www.whitehouse.gov/OMB/circulars/a087/a087-all.html) or A-122 (Cost Principles for Non-Profit Organizations, http://www.whitehouse.gov/OMB/circulars/a122/a122.html), or should contact the grants management officer under INQUIRIES.
   Costs for evaluation activities are allowable, as are costs for the Community and Scientific Advisory Council. All applications must include costs associated with one annual meeting per year in Rockville, MD, of NARCH directors and their key scientific personnel.

Student Development Costs
   Student (graduate, undergraduate, and high school if well justified) remuneration through salary/wages for participation in research experiences may be requested, provided all the following conditions are met.
      * The student is performing necessary work involved in the research.
      * There is employer-employee relationship between the student and the proposed NARCH or its partners.
      *The total compensation is reasonable for the work performed.
      * It is the practice of the proposed NARCH or its partners to provide compensation for all students in similar circumstances, regardless of the source of support for the activity.
   Graduate students are allowed tuition costs as part of a compensation package. When requesting support for a graduate student, the NARCH application should provide, in the budget justification section of the application, the basis for the compensation level. The IHS staff will review the requested compensation level and, if it is reasonable and justified, will provide compensation up to a maximum of $26,000 (additional information is available at: http://grants.nih.gov/grants/guide/notice-files/not98-168.html). Post-doctoral students should be compensated at a rate commensurate with that of other post-doctoral employees with similar degrees and experience at the research-intensive institution.
   It is the expectation of the IHS and NIGMS that students who are enrolled in a Ph.D. program, as part of a

proposed NARCH, will not be excluded from support from other non-federal or federal graduate training sources (such as loans and assistance under the Veterans' Adjustment Benefit Act or Pell Grants) for which they are eligible. Graduate and post-doctoral students cannot concurrently hold another federally-sponsored stipend or fellowship or any other federal award that duplicates the NARCH support.

Faculty Development Costs

Costs to support various activities such as workshops or courses, national meetings, or short-term research experiences in the laboratory of an active NIH-extramurally-funded researcher needed for acquiring specific skills or methodologies needed for prospective research are allowable. Such costs might include tuition, travel and per diem costs, as well as salary support appropriate to the percent effort needed for the activity. Also, allowable are costs such as travel and per diem associated with short-term research experiences in the laboratory of an active extramurally funded researcher.

Research Project Costs

Direct costs associated with research and pilot research projects are allowable when adequate justification is provided. These include faculty salaries, reimbursed according to percent effort. Summer salary support can be paid provided the institution's academic schedule permits such release and when the institution approves. The maximum summer-salary support provided by the program can not exceed the equivalent of two months at 100 percent effort, or time specified by the institution as its policy. Grant funds may not be used to increase or supplement faculty academic year salaries. Salary support for technical assistance and costs for consultants, if justified, are allowable. Costs for equipment to be used to carry out the proposed research are allowable.

Costs for core scientific services to support two or more projects are allowable. Costs for multi-user research equipment are also allowable. A plan for access to the multi-user equipment, its maintenance, management and use must be included. To aid in the review, it is suggested that a tabular summary show the estimated or actual proportional use of this equipment by each project, and other investigators and students. Justify this core component by discussing ways in which these centralized services improve quality, bring about an economy of effort, and/or save overall costs as compared to their inclusion as part of each research project. Personnel costs to maintain and service the equipment are an allowable cost. Support for very large pieces of equipment, however, may be restricted by the NARCH budget. Plans to maintain the shared core scientific services and facility beyond the grant period should be discussed.

Costs for supplies, including costs for animals, necessary to carry out the proposed research may be included. Travel costs for the investigator(s) are permitted when direct benefits to the program are expected, and when adequate justification is provided. Alterations and Renovations costs (up to $40,000) are allowable only when essential for conduct of the proposed research. Other permitted costs include animal maintenance (unit care costs and number of care days), donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, and service contracts.

Also allowable, when fully justified, are consortium arrangements that may involve personnel costs, supplies, and other allowable costs, including F&A costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, data processing, or core administrative services, are allowable expenses.

The intent of pilot research projects is to lead to regular research projects funded as part of the center grant or as freestanding grants. For pilot research projects, applications may request support for up to $35,000 (direct costs) per year. This support is non-renewable.

Subcontracts

The grant recipient may issue subcontracts to other organizations (such as the research-intensive institution of the partnership), as long as at least 30% of the grant remains with the AI/AN organization; that is, no more than 70% may be subcontracted.

Unallowable Costs

Unallowable costs for research projects (including for pilots projects) include costs for student development, textbooks, journals, memberships, and Internet subscription costs, as well as other costs prohibited by OMB Circulars A-87 or A-122 as applicable. Employees of the applicant organization may not serve as paid consultants.

The pilot research project is intended for faculty without current research support. Therefore, investigators with significant current support from other mechanisms such as the R01 and research funding from other extramural sources are not eligible, and the costs therefore are not allowable.

Undergraduate tuition, housing, food, or recruitment expenses of any kind are not allowable under the NARCH

initiative. Support for textbooks, incentives, memberships, and Internet subscriptions are not allowable.

QUALIFICATIONS OF THE NARCH PROGRAM DIRECTOR AND KEY PERSONNEL

As leader of the research and research training for the proposed NARCH, the NARCH Program Director is expected to possess certain essential qualifications: 1. strong leadership skills, including scientific leadership experience and a strong academic and scientific background, as exemplified, ideally, by scientific publications and a record of peer-reviewed scientific support; 2. the knowledge of and personal working relationship with the AI/AN tribes or communities involved in the NARCH research, and with the partners of the proposed NARCH; 3. strong mentoring and supervision skills, to exercise responsibility for mentoring activities, organization of communicating skills programs, special methods workshops, tracking of student career plans, etc.; 4. knowledge of IHS and NIH policies, including those concerning human participants in research, human biological material, animals, hazardous materials, and tribal review and approval of research.

The names and qualifications of the NARCH Program Director, the Student and Faculty Development Director and directors of individual projects within the program (where appropriate), and any other key personnel, shall be listed in the application under Key Personnel, and their Biographical Sketches, including other support, should be included.

REVIEW CONSIDERATIONS

Upon receipt, IHS and NIH staff will administratively review applications for completeness and responsiveness. Applications that are incomplete, non-responsive to this PA, or do not follow the guidelines of the PHS form 398 (Rev. 5/2001) or of the supplementary instructions for NARCH grants, will be returned to the applicant without further consideration.

Applications will be evaluated in accordance with the criteria stated below for scientific and technical merit by appropriate peer review groups convened by the CSR. The National Advisory General Medical Sciences Council will provide the second level of review.

Overall Review of the NARCH

In reviewing the overall Center, the initial scientific review group will examine evidence of the partners' commitment to the purposes of the NARCH initiative: to develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, and behavioral research that is competitive for NIH funding; to increase the capacity of both research-intensive institutions and AI/AN organizations to work in partnership to reduce distrust by AI/AN communities and people toward research; and to encourage competitive research linked to the health priorities of the AI/AN partner and to reducing health disparities. The evidence will include:

* the quality of the partnership of the institutional and community partners, and the quality of the involvement of the Community and Scientific Advisory Council, as demonstrated by documentation of (for instance): the intellectual and tangible contributions and activities of the partners, and of the Council, in developing the application and the proposed NARCH; the interactions of the partners, and of the members of the Council, in meetings (such as those to develop the application and proposed NARCH); the past activities and future plans to increase the capacity of the partners and of the Council; the plans for future contributions and activities by the partners, and by the Council, in furthering the goals of the proposed NARCH; and the plans for future development of the partnership itself;

* the experience and commitment of the institutional and community partners to recruit, retain, and advance AI/AN faculty and students, to support faculty and student research efforts, and to increase the role of the involved AI/AN communities in the plans of the proposed NARCH;

* the appropriateness of the plan for evaluating the impact of the proposed NARCH, including the quality of baseline data and milestones for accomplishments, and a system to track the future course of program participants; and

* the potential of the proposed NARCH to be a regional and national resource, including: capacity to provide quality research training and mentoring for integrated promotion and development of AI/AN research careers from undergraduate (or if well justified, high school) through post-doctoral levels; attainment of quality research linked to health priorities of the AI/AN partner and to reducing health disparities; plans for research information dissemination and education activities; and plans for the development of research networks to support the scientific aims of the proposed NARCH.

Review of Student and Faculty Development Plans

The anticipated effectiveness of the proposed NARCH in making a difference relative to the current base-line

data (based in part on previous experience of the partners) will be assessed. Factors to be considered include:

* the appropriateness of the content, phasing, quality, and duration of the student or faculty development plans in the NARCH application to achieve the scientific development of the faculty, post-doctoral, pre-doctoral, undergraduate, and (if well justified) high school students; and

* the experience, proposed commitment, and quality of the mentoring plan and of individual mentors of the partners in providing mentoring, guidance, and advice to candidates (including training in responsible conduct of research and research integrity, teaching, and protection of human subjects), and in fostering the development of academic and community-based AI/AN researchers.

Review of Research Projects

The NIH has announced procedures to be used for the review of research grant applications (NIH GUIDE, Volume 26, Number 22, June 27, 1997 or see http://grants.nih.gov/grants/guide/notice-files/not97-010.html). For NARCH applications, the five criteria listed in this announcement will be used for the scientific review of research projects and pilot research projects. The review of research projects and pilot research projects will be the same except that applications for pilot studies may be smaller in scope and would not be expected to have preliminary data.

The purposes of the NARCH initiative are: to develop a cadre of AI/AN scientists and health professionals engaged in biomedical and behavioral research; to increase the formation of partnerships between AI/AN and research-intensive institutions; and to encourage competitive research that address the health priorities and health disparities in the AI/AN population. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these purposes. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the application acknowledge potential problem areas and consider alternative tactics? For pilot research projects, are the proposed aims reasonable, and is there potential to lead to more substantial funding?

(3) Innovation: Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

* The adequacy of plans, if research on human subjects is involved, to include both genders and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

* The reasonableness of the proposed budget and duration in relation to the proposed research.

* The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

* The adequacy of the proposed plan to share data, if appropriate.

AWARD CRITERIA

Priorities for funding will be based on the scientific and technical merit of the application, the assessed potential of investigators in the developmental stages of their careers, and the likelihood that the proposed NARCH can further the purposes of the NARCH initiative. Awards will be made only to organizations with financial management systems and management capabilities that are acceptable under PHS policy. Awards will be administered under the PHS Grants Policy Statement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential

applicants is welcome.

Questions on the initiative, especially regarding IHS issues and policies, may be directed to:
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Questions on the initiative, especially regarding NIGMS issues and policies, may be directed to:
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Minority Opportunities in Research Division
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Bethesda, MD 20892-6200
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Questions on the review of applications may be directed to:
Michael R. Martin, Ph.D.
Director, Division of Physiological Systems
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Questions on grants management and fiscal matters may be directed to:
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Grants Management Branch
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AUTHORITY AND REGULATIONS
   This initiative is described in the Catalog of Federal Domestic Assistance Nos. 93.933 and 93.375. Sections 301(a) and 405 of the Public Health Service Act, as amended authorize these awards, and these are administered under PHS grants policies and Federal Regulations 42 CFR part 52c, 45 CFR part 74, and 45 CFR part 92. See also Senate Appropriations Committee Report, No. 92-316, July 29, 1971, Executive Order 12900 , Educational Excellence for Hispanic Americans February 22, 1994, Executive Order 12876, Historically Black Colleges and Universities, November 1, 1993, and Executive Order 13021, October 21, 1996, and Outline of Work Plan, August 18, 1998, White House Initiative on Tribal Colleges and Universities. Applications are not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.
   The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, P.L. 103-227, the Pro-Children Act of 1994, prohibits smoking in

certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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